**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Health Technology Evaluation**

# Icotrokinra for treating moderate to severe plaque psoriasis in people 12 years and over ID6579

**Draft scope**

## Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of icotrokinra within its marketing authorisation for moderate to severe plaque psoriasis in people 12 years and over.

## Background

Plaque psoriasis is an inflammatory skin condition characterised by an accelerated rate of turnover of the upper layer of the skin (epidermis). This leads to an accumulation of skin cells forming raised plaques on the skin. These plaques can be flaky, scaly, itchy and red or a darker colour to the surrounding skin. Plaque psoriasis may affect the scalp, elbows, limbs and trunk and sometimes the face, groin, nails, armpits or behind the knees. Although it is a chronic, persistent, severe condition, its course may be unpredictable, with flare-ups and remissions. In people with darker skin the appearance of psoriasis may be less obvious, and severity may be underestimated.

Psoriasis is generally graded as mild, moderate or severe and takes into account the location, surface area of skin affected and the impact of the psoriasis on the person. The Psoriasis Area and Severity Index (PASI) is an index of disease severity in adults and takes into account the size of the area covered with psoriasis as well as redness, thickness and scaling. In addition, the Children's Dermatology Life Quality Index (CDLQI) and Dermatology Life Quality Index (DLQI) are validated tools that can be used to assess the impact of psoriasis on physical, psychological and social wellbeing on children, young people and adults.

The prevalence of psoriasis in the United Kingdom is estimated to be between 1.3% and 2.8%.[1] The prevalence in adolescents is approximately 1.4% in people aged between 10 and 19 years.[2] About 90% of people with the condition have plaque psoriasis and about 20% have moderate to severe disease (15% moderate, 5% severe),[3] equating to approximately -18,000 adolescents (aged 10 to 19) and 127,000 to 1274,000 adults in England and Wales.[4]

There is no cure for psoriasis but there is a wide range of topical and systemic treatments that can manage the condition. Most treatments reduce the severity of psoriasis flares rather than prevent episodes. Psoriasis has to be treated continually and on a long-term basis. NICE clinical guideline 153 on psoriasis recommends that people with psoriasis should be offered topical therapies such as corticosteroids, vitamin D and vitamin D analogues. For people in whom topical therapy does not alleviate symptoms, the guideline recommends phototherapy (broad- or narrow-band ultraviolet B light) and psoralen with ultraviolet A phototherapy (PUVA). The guideline recommends systemic non-biological therapies (such as, as ciclosporin, methotrexate and acitretin) for people whose psoriasis:

- cannot be controlled with topical therapy **and**

- has a significant impact on physical, psychological or social wellbeing **and**
- one or more of the following apply:
    - psoriasis is extensive **or**
    - psoriasis is localised and associated with significant functional impairment and/or high levels of distress **or**
    - phototherapy has been ineffective, cannot be used or has resulted in rapid relapse.

The guideline notes that methotrexate and ciclosporin do not have UK marketing authorisations for treating psoriasis in children and young people. The guideline recommends that acitretin should only be used in exceptional circumstances for children and young people.

For people with severe psoriasis (as defined by a total PASI score of 10 or more) whose disease has not responded to, or who are intolerant to or contraindicated to standard systemic therapies such as methotrexate or phototherapy, NICE technology appraisal guidance 455 recommends adalimumab, etanercept, ustekinumab in children and young people aged over 4, 6 or 12 years respectively, and NICE technology appraisal guidance 734 recommends secukinumab in children and young people aged between 6 and 17 years old.

Treatment options for adults include etanercept, adalimumab, ustekinumab, secukinumab, apremilast, ixekizumab, dimethyl fumarate, brodalumab, guselkumab, certolizumab pegol, tildrakizumab,risankizumab, bimekizumab and deucravacitinib (NICE technology appraisal guidance 103, 146, 180, 350, 419, 442, 475, 511, 521, 574, 575, 596, 723 and 907); these options are for adults with severe psoriasis whose disease has not responded to, or who are intolerant to or contraindicated to, standard systemic therapies such as ciclosporin, methotrexate, acitretin and PUVA. Technology appraisal guidance 134 recommends infliximab as a treatment option for adults with very severe psoriasis (as defined by a total PASI score of 20 or more and a DLQI score of more than 18) whose disease has not responded to, or who are intolerant to or contraindicated to standard systemic therapies. Biosimilar products of some biological therapies are available for use in the NHS.

**The technology**

Icotrokinra (brand name unknown, Johnson & Johnson) does not currently have a marketing authorisation in the UK for treating moderate to severe plaque psoriasis in people 12 years and over. It has been studied in clinical trials in which icotrokinra has been compared with:

- placebo in people aged 12 years and over with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic treatment.
- placebo and deucravacitinib in adults with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic treatment.

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| **Intervention(s)** | Icotrokinra |
| **Population(s)** | People aged 12 years and over with moderate to severe plaque psoriasis |
| **Subgroups** | • previous use of phototherapy and/or systemic non-biological therapy<br>• previous use of biological therapy |
| **Comparators** | If systemic non-biological treatment or phototherapy is suitable:<br>• Systemic non-biological therapies (including methotrexate, ciclosporin and acitretin)<br>• Phototherapy with or without psoralen<br>For people with severe or very severe psoriasis [defined by a total PASI of 10 or more, and a DLQI of more than 10] for whom systemic non-biological treatment (including methotrexate, ciclosporin and acitretin) and phototherapy are inadequately effective, not tolerated or contraindicated who are<br>Aged 12 years and over:<br>• TNF-alpha inhibitors (adalimumab and etanercept)<br>• IL-12 / IL-23 inhibitor (ustekinumab)<br>• IL-17A inhibitor (secukinumab)<br>• Best supportive care<br>Aged 18 years and over:<br>• TNF-alpha inhibitors (adalimumab, etanercept, certolizumab pegol and infliximab [for very severe plaque psoriasis, as defined by a total PASI of 20 or more, and a DLQI of more than 18] )<br>• IL-17 inhibitors (brodalumab, ixekizumab, secukinumab and bimekizumab)<br>• IL-23 inhibitors (guselkumab, tildrakizumab and risankizumab)<br>• IL-12 / IL-23 inhibitor (ustekinumab)<br>• Tyrosine kinase 2 inhibitor (deucravacitinib)<br>• Apremilast<br>• Dimethyl fumarate<br>• Best Supportive Care |

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| **Outcomes** | The outcome measures to be considered include:<br>• severity of psoriasis<br>• psoriasis symptoms, such as itch, and symptoms on the following areas: face, scalp, nails and joints, and other difficult-to-treat areas including the hands, feet and genitals<br>• mortality<br>• response rate<br>• duration of response<br>• relapse rate<br>• adverse effects of treatment<br>• health-related quality of life. |
| **Economic analysis** | The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.<br>If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out.<br>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.<br>Costs will be considered from an NHS and Personal Social Services perspective.<br>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.<br>The availability and cost of biosimilar and generic products should be taken into account. |
| **Other considerations** | Where the evidence allows, sequencing of different drugs and the place of icotrokinra in such a sequence will be considered.<br>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator. |
| **Related NICE recommendations** | **Related technology appraisals:** |

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| | Deucravacitinib for treating moderate to severe plaque psoriasis (2023) NICE technology appraisal guidance 907<br><br>Secukinumab for treating moderate to severe plaque psoriasis in children and young people (2021) NICE technology appraisal guidance 734<br><br>Bimekizumab for treating moderate to severe plaque psoriasis (2021) NICE technology appraisal guidance 723<br><br>Risankizumab for treating moderate to severe plaque psoriasis (2019) NICE technology appraisal guidance 596<br><br>Tildrakizumab for treating moderate to severe plaque psoriasis (2019) NICE technology appraisal guidance 575<br><br>Certolizumab pegol for treating moderate to severe plaque psoriasis (2019) NICE technology appraisal guidance 574<br><br>Guselkumab for treating moderate to severe plaque psoriasis (2018) NICE technology appraisal guidance 521<br><br>Brodalumab for treating moderate to severe plaque psoriasis (2018) NICE technology appraisal guidance 511<br><br>Dimethyl fumarate for treating moderate to severe plaque psoriasis (2017) NICE technology appraisal guidance 475<br><br>Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people (2017) NICE technology appraisal guidance 455<br><br>Ixekizumab for treating moderate to severe plaque psoriasis (2017) NICE technology appraisal guidance 442<br><br>Apremilast for treating moderate to severe plaque psoriasis (2016) NICE technology appraisal guidance 419<br><br>Secukinumab for treating moderate to severe plaque psoriasis (2015) NICE technology appraisal guidance 350<br><br>Ustekinumab for the treatment of adults with moderate to severe psoriasis (2009) NICE Technology Appraisal 180.<br><br>Adalimumab for the treatment of adults with psoriasis (2008) NICE Technology Appraisal 146.<br><br>Infliximab for the treatment of adults with psoriasis (2008) NICE Technology Appraisal 134.<br><br>Etanercept and efalizumab for the treatment of adults with psoriasis (2006) NICE Technology Appraisal 103. Note: guidance for efalizumab has now been withdrawn.<br><br>**Related NICE guidelines:**<br><br>Psoriasis: assessment and management (2012 updated 2017) NICE guideline CG153 |

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| | **Related NICE guidelines in development:**<br>Psoriasis: assessment and management - Topical therapy. NICE guideline. Publication date to be confirmed<br>**Related quality standards:**<br>Psoriasis (2013) NICE quality standard 40 |

**Questions for consultation**

Where do you consider icotrokinra will fit into the existing care pathway for moderate to severe plaque psoriasis in people 12 years and over?

Please select from the following, will icotrokinra be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would icotrokinra be a candidate for managed access?

Do you consider that the use of icotrokinra can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which icotrokinra will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE is considering evaluating this technology through its cost comparison evaluation process. Please provide comments on the appropriateness of appraising this topic through this process.
(Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

Technologies can be evaluated through the cost-comparison process if they are expected to provide similar or greater health benefits, at a similar or lower cost, compared with technologies that have been previously recommended (as an option) in published NICE guidance for the same indication. Companies can propose cost-comparison topics to NICE at any stage during topic selection and scoping. NICE will route technologies for evaluation through the cost-comparison process if it is agreed during scoping that the process is an appropriate route to establish the clinical and cost effectiveness of the technology.

NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.

- Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators?
- Will the intervention be used in the same place in the treatment pathway as the comparator(s)? Have there been any major changes to the treatment pathway recently? If so, please describe.
- Will the intervention be used to treat the same population as the comparator(s)?
- Overall is the technology likely to offer similar or improved health benefits compared with the comparators?
- Would it be appropriate to use the cost-comparison methodology for this topic?

**References**

1. Springate DA, Parisi R, Kontopantelis E, Reeves D, Griffiths CEM, Ashcroft DM (2016). Incidence, prevalence and mortality of patients with psoriasis: a U.K. population-based cohort study. British Journal of Dermatology. 176: 650–658.

2. Gelfand J, Weinstein R, Porter S et al. (2005) Prevalence and treatment of psoriasis in the United Kingdom A population based study. JAMA Dermatology 141: 1537-1541.

3. Menter A, Korman NJ, Elmets CA et al. (2011) Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol 2011; 65:137–74.

4. Office for National Statistics (2025) Population Estimates for UK, England and Wales, Scotland and Northern Ireland mid-2024. Accessed September 2025.